



Food and Drug Administration
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June 3, 2016

Praxair Distribution, Incorporated
% Ms. Audrey Swearingen
Director, Regulatory Affairs
Emergo Global Consulting, LLC
816 Congress Avenue
Suite 1400
Austin, TX 78701

Re: K153518
Trade/Device Name: Medipure Oxygen-LC System
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: ECX
Dated: May 5, 2016
Received: May 5, 2016

Dear Ms. Swearingen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina Kiang
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for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153518

Device Name
Medipure Oxygen-LC System

Indications for Use (Describe)

The Medipure Oxygen-LC System is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to neonates, pediatrics, and adults. The device is intended for limited duration use, such as would be necessary during patient transport.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 – 510(k) Summary (Special 510(k))

Medipure Oxygen-LC System

K 153518

1. Submission Sponsor

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2. Submission Correspondent

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Email: project.management@emergogroup.com

3. Date Prepared

May 5, 2016

4. Device Identification

Trade/Proprietary Name: Medipure Oxygen-LC System
Common/Usual Name: Medical Gas Delivery System
Classification Name: N/A - Unclassified
Regulation Number: N/A - Unclassified
Product Code: ECX - Cylinder, compressed gas, and valve
Device Class: Unclassified (pre-amendment)
Classification Panel: Anesthesiology

5. Legally Marketed Predicate Device

K132778, Grab 'n Go Plus, Praxair Healthcare Services.

6. Device Description

The Medipure Oxygen-LC System is an integrated medical gas delivery system. The Medipure Oxygen-LC System is comprised of the Cavagna MVA2 series oxygen Valve Integrated Pressure Regulator (VIPR) permanently mounted to a large steel cylinder, either K or T size, and protected by a plastic guard. The Medipure Oxygen-LC System is a result of a design modification to the previously cleared Praxair Grab 'n Go Plus System (K132778).

The Cavagna MVA2 series VIPR is currently used on the Grab 'n Go Plus predicate device. It is compliant with CGA E-18. The plastic shroud is a new design and is compliant with ISO 11117-2008 and DOT Title 49 CFR Part 173.301(h)(3).

The modified design of the Medipure Oxygen-LC System is intended to satisfy customers with high oxygen demands who may not have access to a medical pipeline. The all-in-one concept of the VIPR (used in both the modified and unmodified predicate devices) provides ease of use and convenience over the traditional setup of separate regulator and flow meter.

7. Indications for Use Statement

The Medipure Oxygen-LC System is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to neonates, pediatrics, and adults. The device is intended for limited duration use, such as would be necessary during patient transport.

8. Substantial Equivalence Discussion

The following table compares the Medipure Oxygen-LC System to the unmodified predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence, and supports that the subject device, as modified, does not raise any new issues of safety or effectiveness than the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	Praxair Distribution, Inc. (previously Praxair Healthcare Services)	Praxair Healthcare Services	Significant Differences
Trade Name	Medipure Oxygen-LC System	Grab 'n Go Plus System	
510(k) Number	-	K132778	N/A
Product Code	ECX	ECX	Same
Regulation Number	unclassified	unclassified	Same
Intended Use	Medical gas providing supplemental oxygen, by Rx only, to neonates,	Medical gas providing supplemental oxygen, by Rx only, to neonates,	Same

	pediatrics, and adults.	pediatrics, and adults.	
Indications for Use	The <i>Medipure Oxygen-LC System</i> is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to neonates, pediatrics, and adults. The device is intended for limited duration use, such as would be necessary during patient transport.	The <i>Grab 'n Go Plus System</i> is an integrated delivery system intended to provide supplemental oxygen, by Rx only, to neonates, pediatrics, and adults. The device is MR Conditional, and suitable for use during MR imaging for MRI systems up to 3.0 Tesla. The device is intended for limited duration use, such as would be necessary during patient transport.	Similar. The unsuitability of the Medipure Oxygen-LC steel cylinder for use in an MRI environment is a restriction of the use environment, but does not change the intended use of the device to provide supplemental oxygen, by Rx only, to neonates, pediatrics, and adults.
Medical Gas	Oxygen	Oxygen	Same
Low Flow Setting	Yes	Yes	Same
Contents Gauge Type	Bourdon Tube	Bourdon Tube	Same
Filters	4	4	Same
Service Pressure Max.	3335 psi	3335 psi	Same
Regulator Style	Single Stage Piston	Single Stage Piston	Same
Cylinder Material	High strength Steel	Aluminum	The larger capacity Medipure Oxygen-LC cylinders utilize high strength Cr Mo steel to accommodate the higher stresses. The steel cylinders are industry standard and commonly used for medical gases, thereby raising no new questions of safety and effectiveness.
Cylinder Sizes	K, T	D, E	Medipure Oxygen-LC has larger cylinders to provide a larger oxygen capacity during use. Verification testing shows the larger volume raises no new questions of safety and effectiveness.
Access Ports	Yes	Yes	Same
Flow Selector	Yes	Yes	Same

9. Non-Clinical Performance Data

Internal verification and validation testing confirms that product specifications of the Medipure Oxygen-LC System are met. These are equivalent to those of the predicate device. The testing results support that the device's design changes do not affect the safe and effective use of the device as compared to the unmodified predicate device. Verification testing of the Medipure Oxygen-LC System, in accordance

with design controls, demonstrated the device meets the specifications for its intended use. Verification testing was performed as follows:

- ISO 11117:2008 - Gas cylinders - Valve protection caps and valve guards-Design, construction and tests
- ISO 10524-3, Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves
- 49 CFR §173.301(h)(3) – DOT Cylinder valve protection
- Total Suspended Particulate, Odor and Oxygen Analysis

The device passed all testing and is determined to be substantially equivalent to the unmodified Grab 'n Go Plus device.

10. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device; or the device has the same intended use and different technological characteristics, but can be demonstrated to be substantially equivalent to the predicate device, and does not raise additional questions regarding its safety and effectiveness.

As such, the Medipure Oxygen-LC System, as modified, is determined to be substantially equivalent to the Grab 'n Go Plus predicate device.